REMARKS

In the Office Action dated February 25, 2003, the Examiner has set forth a requirement for restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I.	Claims 1-29, drawn to a preparation of undifferentiated embryonic stem cells and methods of culturing, classified in class 435, subclass 1.1 and class 435, subclass 325.
Group II.	Claims 30-35, drawn to a preparation of somatic cells and a method of producing a somatic cell from an embryonic stem cell, classified in class 435, subclass 1.1 and class 435, subclass 325.
Group III.	Claims 36 and 37, drawn to insulin or insulin analogue induced factor, unclassifiable because the nature of the analogue is not clearly set forth in the claim.

The Examiner alleges that the inventions are distinct, each from the other, because of the following reasons. Specifically, the Examiner contends that Groups I and II are unrelated allegedly because they are drawn to three different and unique types of methods directed to obtaining and maintaining different cell types, i.e., an ES cell, a progenitor cell and a somatic cell, respectively. The Examiner contends that the methods require different materials to practice, require different method steps, and result in materially different products. Additionally, the Examiner contends that Groups I-II are unrelated to Group III, allegedly because the product of Group III, an insulin induced factor, is not present in the composition of cells or used in any of the methods of Groups I-II.

Furthermore, the Examiner states that, if Group I is elected, a further election of species is required. The Examiner contends that the claims encompass patentably distinct species. Specifically, the Examiner contends that claims 7, 16 and 27 recite several structurally unrelated, but functionally related species of an antagonist of BMP-2. The specific species antagonists include fetuin, noggin, chordin, gremlin, follistatin, Cerberus, amnionless, DAN

ectodomain of BMPR1A, ligand binding domain of BMP-2, insulin or an insulin analogue. The Examiner has required Applicant to include an identification of the elected species and a listing of all claims readable thereon, including any claims subsequently added. The Examiner further indicates that, upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

In order to be fully responsive to the Examiner's requirement for restriction, Applicant provisionally elects to prosecute the subject matter of Group I, Claims 1-29, drawn to a preparation of undifferentiated embryonic stem cells and methods of culturing. In connection with the election of Group I, Applicant further elects noggin in response to the requirement for species election. Claims 1-15, 25-27 and 29 read upon the elected species. Applicant reserves the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicant hereby traverses the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present

application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

Specifically, Applicants respectfully submit that the present invention provides a preparation of undifferentiated ES cells sustainable for a prolonged period in an undifferentiated state, as well as methods for maintaining and culturing such ES cells. ES cells have a tendency to differentiate into cells similar to those found in extraembryonic endodermal lineages of the early embryo. If ES cells are not treated to prevent this default differentiation, cells of somatic lineages cannot be obtained effectively. The undifferentiated ES cells cultured in accordance with the present invention are capable of undergoing somatic differentiation to produce progenitor cells and somatic cells. Therefore, the undifferentiated ES cells, the progenitor cells and the somatic cells prepared from such undifferentiated ES cells, as well as methods for preparing and culturing these cells, are related to each other as different aspects of a single invention.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would

require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicant respectfully suggests that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade

and Tariffs (GATT), applicant is required to conduct simultaneous prosecution, as here, requiring excessive filing costs or otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicant respectfully submits that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined three groups, one from the other, as presented by the Examiner.

In view of the foregoing remarks, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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